



DEPARTMENT OF HEALTH & HUMAN SERVICES

94369d  
Food and Drug Administration

Dallas District  
4040 North Central Expressway  
Dallas, Texas 75204-3145

**04-DAL-WL-04**

October 20, 2003

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. Lenny M. Pippen, President  
Schwan's Sales Enterprises Manufacturing, Inc.  
115 West College Drive  
Marshall, Minnesota 56259

Dear Mr. Pippen:

We inspected your firm, Schwan's Sales Enterprises Manufacturing, Inc., located at 1251 Scarborough Lane, Pasadena, Texas, on August 28-29, 2003. The inspection was conducted to determine compliance with FDA's Seafood Hazard Analysis Critical Control Point (HACCP) Regulations, Title 21, Code of Federal Regulations (CFR) Part 123 and the current Good Manufacturing Practice (GMP) requirements for foods, 21 CFR Part 110. We found that you have serious deviations from the Seafood HACCP Regulations. In accordance with 21 CFR §123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or to otherwise operate in accordance with the requirements of 21 CFR Part 123 renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4).

During the inspection, the FDA investigator observed that there were deviations from the principles of HACCP and the significant requirements of the program. You can find the Act and the Seafood HACCP Regulations through links in FDA's homepage at [www.fda.gov](http://www.fda.gov). These deviations, some of which were previously brought to your attention, cause your fully cooked, frozen, ready to eat (RTE), not shelf stable shrimp spring roll product to be adulterated in that they have been packed, prepared, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health.

Page 2 – Mr. Lenny M. Pippen, President  
Schwan's Sales Enterprises Manufacturing, Inc.  
October 20, 2003

These deviations were as follows:

1. You must have a HACCP plan that, at a minimum, lists the critical limits that must be met, to comply with 21 CFR § 123.6(c)(3). A critical limit is defined in 21 CFR § 123.3(c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard." However, your firm's HACCP plan for Seafood Egg Rolls and Appetizers RTE Not Shelf Stable that contain shrimp lists a critical limit of the internal product temperature at [REDACTED] Fahrenheit for [REDACTED] at the cooking critical control point that is not adequate to reach a 6D log reduction of pathogens.

Your firm was previously cited for this same violation by an FDA Investigator during the inspection of your facility on March 11, 2002. A Warning Letter dated February 13, 2001 was issued because of deficiencies from the previous inspection on January 19, 2001. In that letter, you were advised that your firm should address the potential hazard of *Clostridium botulinum* toxin formation for your Modified Atmosphere Packaged shrimp egg rolls and submit private laboratory study information to the FDA. Your firm's response included having a challenge study [REDACTED] entitled, "Microbiological Stability of an Egg Roll Product Challenged with *Clostridium botulinum*," dated July 23, 2001. A copy of this study along with a copy of the "Validation of an Egg Roll Process for the Reduction of *Listeria innocua* and *Listeria monocytogenes*" dated August 4, 2000, was provided to our Investigator during the February 14 - March 11, 2002, inspection of your facility. The FDA's Center for Food Safety and Applied Nutrition (CFSAN), Office of Seafood, reviewed these two reports along with your firm's FDA-483 written response dated April 26, 2002, and their comments were provided to you in the Untitled Letter 2002-DAL-SH-1, dated September 30, 2002.

Although you made the decision to make corrections to control the HACCP hazard of *Clostridium botulinum* toxin formation and pathogen control for *Listeria innocua* and *Listeria monocytogenes* by the discontinuation of the manufacturing of Modified Atmosphere Packaged shrimp egg rolls, the current inspection discovered that you now produce the seafood product "Shrimp Spring Rolls, Keep Frozen." Your HACCP plan in use is for Seafood Egg Rolls and Appetizers RTE Not Shelf Stable, not for Shrimp Spring Rolls RTE Not Shelf Stable.

Specifically, you continue to use a [REDACTED] directed toward *Salmonella* while *Listeria* are considered to be the most heat resistant of the vegetative pathogens; therefore, the use of the [REDACTED] cook is still not appropriate. If you do not want to use the time and temperature recommendations in The Fish and Fisheries Hazards and Control Guide, *Third Edition*, for inactivating *Listeria* and you do not have any other scientific reference for inactivating *Listeria*, you need to conduct an inoculated pack study to determine the D value for *Listeria monocytogenes* in your product. This is done in a laboratory or pilot plant using *Listeria monocytogenes* in your shrimp spring rolls. The D value will apply provided you do not change your product formulation. A heat penetration study is then done in the plant using the shrimp spring rolls under actual processing conditions to determine the critical limits required to achieve the 6D cook. Please refer to the September 30, 2002 Untitled Letter for the comments by CFSAN's Office of Seafood.

2. You must have a HACCP plan that, at a minimum, lists monitoring procedures for each critical control point to comply with 21 CFR § 123.6(c)(4). However, your firm's plan for Shrimp Egg Rolls RTE Not Shelf Stable lists a monitoring procedure/frequency at the cooking critical control point that is not adequate to control the growth of pathogens.

Your firm monitors the cooking step by inserting a calibrated thermometer into the product once it leaves the cooking oil. The product must maintain [REDACTED] Fahrenheit for [REDACTED] or the product is undercooked. The Fish and Fisheries Hazards and Control Guide, *Third Edition*, states that the cooking operation must be under continuous monitoring or an equivalent procedure. The product's internal temperature at the end of the cooking cycle is not ordinarily a suitable critical limit because of variability from unit to unit.

3. You must provide all mandatory records for official review and copying at reasonable times to comply with 21 CFR § 123.9(c). However, a representative at your firm, [REDACTED] refused to provide for photocopying the HACCP plan or any documents in the HACCP notebooks for processing shrimp egg rolls/spring rolls. Instead, our investigator hand-copied the records in order to conduct his review.

Page 4 – Mr. Lenny M. Pippen, President  
Schwan's Sales Enterprises Manufacturing, Inc.  
October 20, 2003

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific steps you are taking to correct the noted violations and to prevent their recurrence. Please include in your response documentation such as your HACCP plan, corrective actions, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, please explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP Regulations, and the GMP regulations. You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Carolyn A. Pinney, Compliance Officer, at the above letterhead address. If you have any questions regarding any issue in the letter, please contact Carolyn A. Pinney at (214) 253-5312.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael A. Chappell", with a stylized flourish at the end.

Michael A. Chappell  
Dallas District Director

MAC:cap

Page 5 – Mr. Lenny M. Pippen, President  
Schwan's Sales Enterprises Manufacturing, Inc.  
October 20, 2003

cc:  
Mr. William McCormack  
Vice President of Operations  
Schwan's Enterprises Manufacturing Inc.  
115 West College Drive  
Marshall, Minnesota 56259

Mr. Robert G. Treford  
Operations Manager  
Schwan's Enterprises Manufacturing Inc.  
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Pasadena, Texas 77506